53 pgs

DEPARTMENT OF HE TH & HUMAN SERVICES

M1005N

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-65

June 18, 1997

Mr. Robert D. Malouf
Executive Vice President
Cheminova America Corporation
6073 N.W. 167th Street
Unit C-20
Miami, Florida 33015

Dear Mr. Malouf:

This letter is in reference to Skin-Cap® Shampoo, which contains the active ingredients, zinc pyrithione and menthol, and is distributed by your firm. This product is offered for over-the-counter (OTC) sale and promotional labeling for this product designates its use for the treatment of dandruff and seborrheic dermatitis. Because of these labeling claims, the product is a drug as described in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Skin-Cap® Shampoo is subject to final regulations on Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis (Title 21, Code of Federal Regulations, Part 358.701 to 750) which became effective on December 4, 1992. The product contains menthol as an active ingredient, which is not permitted by the monograph for dandruff and seborrheic dermatitis treatment, and it is not labeled in conformance with the final monograph. Therefore, this product is a new drug as referenced in Section 201(p) of the Act. As a new drug, the product, Skin-Cap® Shampoo, may not be legally marketed in the United States without an approved New Drug Application (NDA) as described in Section 505 of the Act. Further, the product is misbranded for not including adequate directions for use as cited in Section 502 of the Act.

The violations cited in this letter are not intended to constitute an all-inclusive list of the violations that may exist for products marketed by your firm. A review of all your firm's products for compliance with the requirements of the Act should be conducted. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of government contracts.

We request that you take prompt action to correct these violations. Failure to promptly correct them may result in Food and Drug Administration initiated regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to the Food and Drug Administration, Florida District, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, Attn: Martin E. Katz, Compliance Officer, (407) 648-6823, ext. 262.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District

cc: [redacted]